

EXHIBIT R



March 30, 2020

Via Email

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Re: United States v. Holmes and Balwani, Case No. 18-cr-00258-EJD
Outstanding Production of FDA and CMS documents

Dear Bob:

This letter responds to your letter of February 7 responding to my February 3 letter addressing serious deficiencies with the government's production of FDA documents. This letter also responds to your March 2 letter to Steve Cazares responding to his February 12 letter about other deficiencies with the government's production of CMS documents. We continue to have grave concerns about the government's approach to those productions, which does not appear to have changed since the Court ruled on November 5, 2019 that these productions fall within the government's Rule 16 obligations. Instead, we see the government taking the same "hands off" approach as before the Court's order, leading to the same lack of confidence we had then. Indeed, even as the problem has become worse, as discussed below, the government has now changed its tune from trying to convince the Court on January 13, 2020 that the FDA is not a major issue in this case ("This is not a case about the FDA." 1/13/20 Transcript at 39) to mentioning FDA 17 times in its March 23, 2020 Bill of Particulars.

The Government's Production of FDA Documents

The depositions of FDA witnesses in the second half of January 2020 revealed intentional withholding of obvious *Brady* evidence from core custodians and a failure to conduct a thorough search for the most important material from a handful of the most important custodians. When we brought some of these issues to the government's attention in my February 3 letter, within four days the government was able to find some of the withheld *Brady* material within the FDA.



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For example, with your February 7 letter the government produced, for the first time, a September 2014 draft request “for cause” inspection of Theranos’ Newark and Palo Alto locations related to its nanotainer and analyzer devices. *See* US-FDA-0040733-53. Previously, on October 1, 2019, the government produced an October 1, 2014 email about the for-cause inspection with only a placeholder document denoting that the attachment was “Intentionally Withheld” by FDA. *See* FDA-0025024-FDA0025026; *see also* US-FDA-0019231 (same email and no attachment produced); US-FDA-0019386 (9/30/2014 email attaching “Theranos Inspection Request Clean” and no attachment produced). Equally concerning is the withholding of certain drafts of FDA minutes until the government’s February 7 production. *See, e.g.,* USA-FDA-0040722-US-FDA0040732.

The decision, by the FDA’s own admission, to “intentionally” withhold *Brady* evidence casts grave doubt on the integrity of the government’s production and on whether all Rule 16 and *Brady* material has been or will ever be produced. This is particularly troubling in view of the fact the government repeatedly represented to the Court that the FDA’s production was complete or nearly complete. *See e.g.,* 10/2/2019 Transcript at 4:10-14 (Mr. Bostic: “My understanding is that … the agencies are still on track to complete their productions of responsive documents either today or in the very near future.”); *id.* at 4:23-5:1 (Mr. Bostic: “The government’s understanding is that the defense will have all novel, nonduplicative and discoverable information either today or within the next few days.”); Dkt. No. 121 at 3 (September 30, 2019 Joint Status Memo) (“As to FDA, the agency expects to be in substantial compliance with the Court’s order as of October 2.”).

The documents that surfaced on February 7 are so critical that it is astonishing they were not produced far earlier—if there was anything that the government should have been collecting and producing, it was these documents from a handful of the most important FDA custodians who handled matters relating to Theranos. But for the civil depositions, it is likely that these documents would have continued to be concealed from the defense. At this point, we have—and the Department of Justice should also have—no confidence in the basic integrity of the FDA’s document production or ability to meet the government’s obligations. We therefore request that the Department of Justice (not the FDA) certify, after a thorough review, that all documents responsive to the Court’s November 5 order from at least the Tier 1 custodians identified by



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Mr. Balwani have been produced. The government must take a hands-on approach to the FDA's collection and production efforts that so far appears to be lacking.

In the same vein, the FDA's November 26, 2019 letter report explaining the corruption of Dr. Alberto Gutierrez's email files is—based on deposition questions to Dr. Gutierrez that the government apparently failed to ask—egregiously incomplete. Dr. Gutierrez was the leader of the FDA team that handled Theranos matters and is among the most core of the core custodians. The FDA's November 26 letter, and your March 11, 2020 email on the topic, discussed only the FDA's e-discovery teams' efforts on Dr. Gutierrez's PST files. Yet at his deposition, Dr. Gutierrez testified that he backed up all his Theranos materials on a hard drive and a CD. Gutierrez Tr. 28:21-30:21; 52:5-53:16. As of October 13, 2017—well after the government's summer 2017 preservation notice to the FDA—the hard drive was apparently in the office of an FDA lawyer named Steve Tjoe, but the government has provided no information about what happened to it after that. *See* US-MISC-000004 (DOJ preservation notice); FDA-0061942 (Dep. Ex. 306A).

There is no indication that the FDA ever looked for the hard drive and CD. The government now claims that it is looking into the matter, but has not stated when that inquiry will be complete. Where is the hard drive and CD? Did the government lose or discard these items for this key custodian? Why didn't the FDA's November 26 report say anything about the hard drive or CD? Why has this emerged only because of questions asked of Dr. Gutierrez at a civil deposition? These questions demand answers that neither the FDA nor the Department of Justice have offered.

Further, the FDA's document collection process appears to fall far below best practices. FDA witnesses testified about the self-collection process they used to search for documents related to Theranos. *See, e.g.*, Pilcher Tr. at 22:24-25 ("I collected the documents, searched for the documents that the request asked for."); Lias Tr. at 28:8-10 and 26:23-24 ("My typical practice is to, to the best of my ability, look at the request and fulfill it to the best of my ability. . . . Typically, we are asked to look [for documents] ourselves."); Hole Tr. at 17:4-8 ("I segregated all my e-mails into a folder and held them there."); Gutierrez Tr. at 51:12-13 (testifying that he searched for and collected documents from his "own decisions of what would be relevant"). No FDA witness knew of any forensic imaging or electronic extraction of communications or other



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documents stored on computers. Nor did any deposed FDA witness recall receiving any assistance or supervision during their collection efforts. *See, e.g.*, Pilcher Tr. at 31:16-25 (testifying that he did not remember anyone assisting him). At a minimum, we would have expected the government to have conducted custodian interviews of the Tier 1 custodians (a common practice when complying with government subpoenas on the defense side).

Despite asking the government to provide more detail about the FDA's recent collection efforts, the defense has received no information about the nature of any electronic collection methodology the government is purportedly using for all FDA custodians in response to the Court's Order (except for Agent Scavdis and the 23 previously disclosed custodians whom the FDA and United States explained would be conducting a manual collection). Absent a more robust and transparent e-discovery protocol, there is no assurance that the government will ever comply fully with the Court's November 5 order.

Because of this disturbing history, Mr. Balwani can have no confidence that the government, relying on FDA, has taken the steps necessary to comply with its Rule 16 obligations and the Court's order. This is particularly true for Tier 1 custodians. The defense cannot "wait and see" whether the government can complete a production that it says has been on the verge of completion since at least the middle of 2019. Accordingly, the Department of Justice must truly get hands-on to ensure and certify that all documents required under the Court's November 5 order have been produced, prioritizing the Tier 1 custodians at the very least.

The Government's Production of CMS Documents

We appreciate your effort to respond to the concerns in our February 12, 2020 letter regarding the production of CMS documents, and that your inquiry regarding documents from the Arizona Department of Health Services remains outstanding. Your representations regarding the production of CMS documents, however, failed to detail how material responsive to the Court's order was identified and collected, failed to confirm that custodians were not each charged with locating and identifying responsive documents, and continues to assert that your production of documents under the Court's order remains subject to the whims of CMS regarding what to produce. This is unacceptable and contrary to your obligations under the Court's order.



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First, please confirm that your representation that a “centralized electronic collection was used for all CMS custodians” means all electronic files, including network, stand-alone digital devices, and hard copy files, were searched electronically using, at a minimum, the search terms previously disclosed in the October 21, 2019 email and attachment from former Assistant United States Attorney Allison Daw. Please also confirm that these searches were conducted by personnel not connected to the Theranos matter—that is, not by the same custodians whose files are the subject of your “centralized electronic collection.”

Second, your assertion that CMS lacks control over CMS confidential documents possessed by current employees who used personal digital devices and/or email accounts for CMS business defies logic and is another example of the government’s disregard and flouting of its obligations under the Order. CMS documents produced to date show that both Karen Dyer, the Director of the Division of Clinical Laboratory Improvement and Quality of CMS, and one of her deputies in the CLIA program at CMS, Sarah Bennett, sent confidential, nonpublic copies of Form 2567 survey reports regarding Theranos, and other documents relating to Theranos, to private email addresses apparently under their control at a time of great public and media scrutiny of Theranos’s laboratories. What inquiry did you make into what Ms. Dyer and Ms. Bennett did with these documents? Did you, the FBI, or anyone on your team investigate whether Ms. Dyer or Ms. Bennett shared these confidential CMS documents with others outside of CMS, including members of the media? These actions undoubtedly violated CMS policies and possibly federal law, as well as risked the disclosure of Theranos’s trade secrets and confidential corporation information when such information was highly sought after.

As you know, Ms. Dyer is the head of the CLIA program that led the charge in seeking revocation of the Theranos laboratories’ CLIA certificates. Now that the government knows, through the defense’s investigation, that documents subject to the Order were disseminated by CMS employees to email networks outside of CMS, the government has an obligation to investigate and identify any further documents subject to the Order and in the possession of CMS employees, via personal email account or otherwise. Your investigation to date appears limited to asking the employees at issue to “voluntarily” review personal devices and accounts and relying on Ms. Dyer’s belief that the only email relating to Theranos in her personal accounts were sent from her CMS account. This reliance on Ms. Dyer’s belief or recollection is insufficient, as demonstrated in her failure to provide a plausible explanation in her January 28,



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2020 deposition for why she sent confidential CMS documents to her personal email address. Accordingly, please confirm that you will further investigate this issue consistent with your obligations under the Order.

Third, your response to our request for metadata missing from the last and largest CMS production on December 31, 2019, that we “have it as the government has it” is remarkably blasé about the government’s obligations under the Order. We understand that you are following-up on this issue. Nonetheless, we reiterate our request for production of the missing metadata necessary to make the documents usable or, at a minimum, a thorough explanation of the technical reasons why metadata was not and cannot be produced.

Fourth, please advise of the status of your inquiry with the Arizona Department of Health Services (AZDHS) regarding Theranos-related documents, including any communications with third parties and/or the media. Please also advise if response to the COVID-19 pandemic may delay any response by AZDHS to this request.

Lastly, we appreciate your producing an unredacted copy of the email CMS048173 and apparent agreement that the previous assertion of the attorney-client privilege was inapplicable. But that unredacted document—an email between Ms. Dyer and counsel for CMS in August 2016—later forwarded by Ms. Dyer to a former CMS employee, is troubling for several reasons. That CMS counsel deemed the document privileged in the first place when non-CMS personnel were involved in the exchange on page one of the document is inexplicable. This error was compounded upon review of the rest of the document, which involves communication about a request by the SEC for assistance in identifying a CLIA expert for the SEC’s investigation. This underlying communication is plainly not related to legal advice sought or given within CMS. As you know, that an attorney is involved in a communication does not render the communication privileged. These judgments require us to ask whether CMS used similar analysis in redacting or withholding other Theranos-related documents subject to the Order. We expect that we will have further questions about this issue after we receive and review the promised CMS privilege log of redacted documents/emails, identified by the defense, that appear to have not included any attorneys as parties to the communication.



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We appreciate your prompt response to these issues.

Very truly yours,

A handwritten signature in blue ink that reads "Jeffrey B. Coopersmith".

Jeffrey B. Coopersmith

cc: Lance Wade